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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,674	10/27/1999	MICHAEL NEHLS	8535-029-999	4973

20583            7590            09/03/2002  
PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 100362711

EXAMINER
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MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
25	

DATE MAILED:

*Below is a communication from the EXAMINER in charge of this application*

**COMMISSIONER OF PATENTS AND TRADEMARKS**

**ADVISORY ACTION**

THE PERIOD FOR RESPONSE:

a)  is extended to run \_\_\_\_\_ or continues to run \_\_\_\_\_ from the date of the final rejection  
b)  expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

Appellant's Brief is due in accordance with 37 CFR 1.192(a).

Applicant's response to the final rejection, filed 8/15/02, has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1.  The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

a.  There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.  
b.  They raise new issues that would require further consideration and/or search. (See Note).  
c.  They raise the issue of new matter. (See Note).  
d.  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.  
e.  They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *The proposed amend raises new issues due to focusing on a specific set of high stringency of deduction conditions out of a plurality of such sets of conditions described in the Sub Spec. on page 11, line 18 through page 12, line 10. The examination of the proposed clm 14 content would clearly require further consideration and/or search.*

2.  Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3.  ~~the proposed amendment~~, the proposed amendment  will be entered  will not be entered and the status of the claims will be as follows:

Claims allowed: None

Claims objected to: None

Claims rejected: 3 and 10-14

However;

Applicant's response has overcome the following rejection(s): \_\_\_\_\_

4.  The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because *of reasons of record as fully discussed in response to applicant's arguments as attached thereto.*

5.  The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

The proposed drawing correction  has  has not been approved by the examiner.

Other *The Formal Drawings filed 8/15/02 have been approved.*

109428,674

PTOL-303 (REV. 5-89)

Further Explanation of Item 4 on the attached Advisory Action:

The rejection of claims 3 and 10-14 under 35 U.S.C. § 101, and the related rejection of these claims under 35 U.S.C. § 112, first paragraph, is maintained. Applicants argue that the gene trapping method as discussed causes the survival and propagation of teratocarcinoma cells with only one non-disrupted allele and thus indicates that these loci are preselected for transfection involving gene functions largely in later stages of cell differentiation and development. In response these are allegations without factual support regarding gene function stages etc. Also, applicants have not supplied any information as to whether the gene being trapped has any cell survival function or not regarding allelic disruption. Due to the huge number of genes in a cell the disruption of one or both alleles for the multitude of non-essential genes will not have any cell survival or differentiation effects. Applicants have not supplied any scientific logic, much less results, to support any relationship between trapped genes as to survival or differentiation, or, for essentiality of gene function, for that matter. Further research is required to determine such function etc. An invention which requires further research in order to have currently available utility fails to meet the utility requirements under 35 U.S.C. § 101 as also already explained in

the previous office action, mailed 8/15/01. Applicants then go on to set forth special characteristics of teratocarcinoma cells but again fail to establish any link between the claimed invention as any of these characteristics. Applicants then argue that gene trap methods are "likely" to be essential to survival of teratocarcinoma cell survival. Going from "likely" to "are" essential requires further research and thus again fails to support the utility requirements under 35 U.S.C. § 101.

Applicants then assert probe utility but again without indicating what result is determinable by such probe usage again requiring further research. It is confusing as to why applicants seem reluctant to perform the appropriate research to convert at least one of the alleged utilities into currently available form as required under 35 U.S.C. § 101. Applicants then admit that the loci may be usable for correlation type research into later stages of cell differentiation and development. Again the need for such research in order to determine a specific and substantial utility supports this rejection. Applicants lastly argue that poorly expressed genes can be identified by the gene trap method. Again such genes are not associated with any specific or substantial utility thus supporting the maintaining of these rejections under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

The lack of written description rejection of claims 3 and 10-14 under 35 U.S.C. § 112, first paragraph, is also maintained. Applicants argue that polynucleotides corresponding to SEQ ID Nos. 9-18 are fully described but that claims which broadly include other sequences also have written description via functional characteristics such as hybridization, restriction maps, antibody cross-reactivity, etc. through a long list. In response this rejection is based on a lack of written description due to a lack of sequence disclosure beyond SEQ ID Nos. 9-18. The above arguments have not pointed to any such sequences beyond SEQ ID Nos. 9-18 and thus are allegations of such broader written description without factual support. This rejection therefore is still deemed proper and maintained as noted above.

No claim is allowed.

It is noted that an Appeal Brief has been submitted, filed 8/15/02, and will be responded to shortly.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 3, 2002

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER